

CONFIDENTIAL
EXHIBIT C

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SUN PHARMACEUTICAL INDUSTRIES)
LTD. and RANBAXY SIGNATURE, LLC,)
)
)
Plaintiffs,)
)
)
v.)
) C.A. No. 1:18-cv-648 (WCB)
SAPTALIS PHARMACEUTICALS, LLC,)
)
)
Defendant.)
)
)

PLAINTIFFS' INITIAL INFRINGEMENT CLAIM CHART

Plaintiffs Sun Pharmaceutical Industries Ltd. and Ranbaxy Signature, LLC (together, “Plaintiffs”), hereby serve on Defendant Saptalis Pharmaceuticals, LLC (“Saptalis”) the following initial infringement claim chart pursuant to Paragraph 4(c) of the Default Standard for Discovery.

In accordance with Paragraph 4(c), these disclosures include a preliminary claim chart relating Saptalis’s ANDA product to the asserted claims of U.S. Patent No. 6,890,957 (the “957 patent”). These disclosures are based on currently available information. Plaintiffs’ investigation in this action is ongoing, and fact discovery has only recently commenced. Plaintiffs therefore provide citations only to evidence demonstrating Saptalis’s infringement that is currently available to Plaintiffs. These disclosures are not intended to be an exhaustive citation of all evidence. Plaintiffs anticipate that additional facts that they learn over the course of the litigation, together with the expected testimony of expert witnesses in this case, will be highly relevant to Saptalis’s infringement. Accordingly, Plaintiffs reserve the right to supplement, modify, and/or enlarge the following disclosures, without prejudice, based on additional documents, information or things, further analysis, and/or in light of subsequent events in the litigation, such as rulings by the Court.

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

Plaintiffs also reserve the right to rely on and introduce information in addition to any information provided herein during discovery, at trial, or otherwise. Plaintiffs further reserve the right to rely on expert discovery and/or testimony to support Saptalis's infringement of the asserted claims.

Asserted Claims of the '957 Patent. Saptalis's submission of ANDA No. 211309 constitutes infringement of claims 1-2, 7, and 9-15 of the '957 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Saptalis commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States the ANDA product disclosed in ANDA No. 211309, or induces or contributes to any such conduct, it would further infringe claims 1-2, 7, and 9-15 of the '957 patent under 35 U.S.C. § 271(a), (b), and/or (c).

Accused Product. The accused product is Metformin Hydrochloride Oral Solution 500 mg/5 mL, disclosed in ANDA No. 211309 (the "ANDA product"). March 16, 2018 Notice Letter Concerning Saptalis ANDA No. 211309 (the "3/16/18 Notice Letter") at 1; Saptalis ANDA at 3.2.P.1 (*Description and Composition of the Drug Product*) p. 2.

Initial Infringement Claim Chart for the '957 Patent. Attached as Exhibit A is Plaintiffs' initial infringement claim chart identifying where each element of the asserted claims is found in Saptalis's ANDA product. In its 3/16/18 Notice Letter, Saptalis has failed to identify any evidence, or has identified insufficient evidence, to support its non-infringement contentions with respect to the specific elements of each asserted claim. Additionally, Saptalis has not yet provided its complete ANDA, samples of the proposed ANDA product, or proposed a construction of any claim terms. Moreover, fact discovery is ongoing. Accordingly, the initial infringement chart set forth in Exhibit A is necessarily limited by Saptalis's incomplete disclosure of information to date regarding its ANDA product. Plaintiffs expressly reserve the right to

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

supplement and/or amend these initial infringement claim charts as fact discovery continues, and in light of expert discovery.

OF COUNSEL:

Charles B. Klein
WINSTON & STRAWN LLP
1700 K. Street NW
Washington, D.C. 20006
(202) 282-5000

Bryce A. Cooper
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5600

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (No. 3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

*Attorneys for Plaintiffs Sun Pharmaceutical
Industries Ltd. and Ranbaxy Signature, LLC*

Dated: October 18, 2018

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

Exhibit A: Initial Infringement Claim Chart – U.S. Patent No. 6,890,957

U.S. Patent No. 6,890,957 (the “957 Patent”)	Saptalis’s ANDA Product
1. A liquid pharmaceutical composition for oral administration which comprises a therapeutically effective amount of metformin or its pharmaceutically acceptable salt;	Saptalis’s ANDA Product is a liquid pharmaceutical composition for oral administration. See, e.g., Saptalis ANDA at 3.2.P.1 (<i>Description and Composition of the Drug Product</i>) pp. 2, 4-7; Saptalis ANDA at Product Development Report pp. 17, 20.
a sweetener that does not increase the blood glucose level of a subject after ingestion thereof;	Saptalis’s ANDA Product contains [REDACTED] See, e.g., Saptalis ANDA at Product Development Report pp. 19, 28.
a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight;	Saptalis’s ANDA Product contains [REDACTED] See, e.g., Saptalis ANDA at Product Development Report pp. 19, 28. [REDACTED] [REDACTED] [REDACTED] [REDACTED] and so [REDACTED]

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

<p>a mineral acid and bicarbonate salt both present in sufficient amounts to maintain the pH of the composition in the range of about 4.0 to about 9.0;</p>	<p>and a pharmaceutically acceptable liquid carrier.</p>	<p>2. The liquid pharmaceutical composition according to claim 1,</p>	<p>wherein the pharmaceutically acceptable carrier is water.</p>	<p>7. The liquid pharmaceutical composition of claim 1,</p>	<p>wherein the polyhydroxy alcohol is present in amounts ranging from about 15% to about 40% by weight.</p>	<p>See above response to claim 1.</p>	<p>Saptalis's ANDA Product contains [REDACTED]. See, e.g., Saptalis ANDA at Product Development Report p. 17-18, 21.</p>	<p>Saptalis's ANDA Product contains [REDACTED]. See, e.g., Saptalis ANDA at 3.2.P.1 (<i>Description and Composition of the Drug Product</i>) p. 4.</p>	<p>Saptalis's ANDA Product contains [REDACTED]. See, e.g., Saptalis ANDA at 3.2.P.1 (<i>Description and Composition of the Drug Product</i>) p. 4.</p>	<p>Saptalis's ANDA Product contains [REDACTED]. See, e.g., Saptalis ANDA at Product Development Report pp. 19, 28.</p>	<p>See above response to claim 1.</p>
<p>9. The liquid pharmaceutical composition of claim 1,</p>									<p>and so</p>	<p>infringe claim 7 of the '957 patent under the doctrine of equivalents. See, e.g., <i>Intendis GMBH v. Glenmark Pharm. Inc.</i>, USA, 822 F.3d 1355, 1361 (Fed. Cir. 2016); <i>Retro Gainesville LLC v. Activis Labs. FL, Inc.</i>, No. CV 14-1118-GMS, 2017 WL 1064883 at *5 (D. Del. Feb. 24, 2017).</p>	

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

<p>wherein the sweetener is a sugar alcohol or non-nutritive sweetener.</p> <p>10. The liquid pharmaceutical composition of claim 1, wherein the polyhydroxy alcohol contains 2 to 6 carbon atoms and contains 2 to 6 hydroxy groups.</p>	<p>Saptalis's ANDA Product contains [REDACTED]. See, e.g., Saptalis ANDA at Product Development Report pp. 19, 28; [REDACTED], Handbook of Pharmaceutical Excipients (6th ed.) at [REDACTED].</p> <p>See above response to claim 1.</p> <p>Saptalis's ANDA Product contains [REDACTED].</p> <p>See, e.g., Saptalis ANDA at Product Development Report pp. 19, 28; [REDACTED], Handbook of Pharmaceutical Excipients (6th ed.) at [REDACTED]; [REDACTED], Handbook of Pharmaceutical Excipients (2d ed.) at [REDACTED].</p>
<p>11. The liquid pharmaceutical composition of claim 1, wherein the polyhydroxy alcohol is a polymer having a molecular weight ranging from 200 to 2000 daltons and has a repeating unit of 2 to 6 carbon atoms and the repeating unit contains 2 to 6 hydroxy groups.</p>	<p>See above response to claim 1.</p> <p>Saptalis's ANDA Product contains [REDACTED].</p> <p>See, e.g., Saptalis ANDA at Product Development Report pp. 19, 28; [REDACTED], Handbook of Pharmaceutical Excipients (6th ed.) at [REDACTED].</p> <p>See above response to claim 1.</p> <p>Saptalis's ANDA Product contains [REDACTED].</p>
<p>12. The liquid pharmaceutical composition according to claim 1, wherein the mineral acid is hydrochloric acid, nitric acid, or sulfuric acid.</p>	<p>See, e.g., [REDACTED]. See, e.g., Saptalis ANDA at 3.2.P.1 (<i>Description and Composition of the Drug Product</i>) p. 4; Saptalis ANDA at Product Development Report p. 19.</p>

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

13. The liquid pharmaceutical composition according to claim 12	<i>See</i> above response to claim 12.
[w]herein the mineral acid is hydrochloric acid.	Saptalis's ANDA Product contains [REDACTED]. <i>See, e.g., Saptalis ANDA at 3.2.P.1 (Description and Composition of the Drug Product) p. 4; Saptalis ANDA at Product Development Report p. 19.</i>
14. The liquid pharmaceutical composition according to claim 1	<i>See</i> above response to claim 1.
[w]herein the pH ranges from about 4.2 to about 7.0.	Saptalis's ANDA Product has [REDACTED]. <i>See, e.g., Saptalis ANDA at Product Development Report p. 17.</i>
15. The liquid pharmaceutical composition according to claim 1	<i>See</i> above response to claim 1.
wherein the bicarbonate salt is potassium bicarbonate.	Saptalis's ANDA Product contains [REDACTED]. <i>See, e.g., Saptalis ANDA at 3.2.P.1 (Description and Composition of the Drug Product) p. 4.</i>

Case 1:18-cv-00648-WCB Document 40 Filed 10/18/18 Page 1 of 2 PageID #: 425

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NOTICE OF SERVICE

PLEASE TAKE NOTICE that, on October 18, 2018, a copy of Plaintiffs' Initial Infringement Claim Chart [CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER] was served on the following counsel via electronic mail:

Kenneth L. Dorsney (#3726)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801-1494
(302) 888-6800
kdorsney@morrisjames.com

Steven D. Roth
David Galluzzo
Thomas Vetter
LUCAS & MERCANTI, LLP
30 Broad Street, 21st Floor
New York, New York 10004
(212) 661-8000 (ext. 103)
sroth@lmiplaw.com

Case 1:18-cv-00648-WCB Document 40 Filed 10/18/18 Page 2 of 2 PageID #: 426

OF COUNSEL:

WINSTON & STRAWN LLP
Bryce A. Cooper
35 W. Wacker Drive
Chicago, Illinois 60601-9703
(312) 558-5600
bcooper@winston.com

WINSTON & STRAWN LLP
Charles B. Klein
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000
cklein@winston.com

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

*Attorneys for Plaintiffs Sun Pharmaceutical
Industries Ltd. and Ranbaxy Signature, LLC*

Dated: October 18, 2018